

REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Claims 44, 96, 98, 133-135 and 137-146 have been cancelled, without prejudice. No other amendments have been made. In view of the amendments and the following remarks, it is believed that all rejections are overcome and that this application is in condition for allowance.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 34-38, 41-43, 95, 97, 110-114, 123-132 and 136
2. Claim(s) cancelled: 1-33, 39, 40, 44-94, 96, 98-109, 115-122, 133-135 and 137-146
3. Claim(s) added: None
4. Claims withdrawn from consideration but not cancelled: None

Interview Summary

The undersigned attorney would like to thank Examiner Bristol for the courtesy of the telephonic interview on November 23, 2010. The obviousness rejections were generally discussed, and it was agreed that these rejections would be removed pending a formal response, which is presented below. The obviousness-type double patenting rejection was also generally discussed, although no agreement was reached with respect to this rejection.

Double Patenting

Claims 34-38, 42, 43, 95, 110, 111, 113, 114, 123-132 and 136 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 98-109 of U.S. Patent Application No. 09/852,547. Applicants are submitting a terminal disclaimer concurrently herewith, thus rendering the double patenting rejection moot.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 34-38, 42, 43, 95, 97, 110, 111, 113, 114, 123-132 and 136 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Furuya et al (Cancer Research, December 1989, Vol. 49, pp 6670-6674) in view of Hoffman ('The Biochemistry of Clinical Medicine', 1970,

pages 48-55). Claims 41 and 112 are objected to. The Examiner contends that Furuya et al. teach that a bovine serum albumin fraction containing globulin remnants inhibited cell growth but that globulin-free bovine serum albumin did not inhibit cell growth. The Examiner then reasons that one skilled in the art would reasonably conclude that serum globulins were the cause of the growth inhibition. The Examiner also contends that Furuya et al. teach that estradiol can overcome this inhibition. The Examiner acknowledges that Furuya et al. fail to teach growth stimulation by estrogen in the presence of IgA or IgM but suggests that Hoffman et al. provides evidence that these components are present within the globulin fraction of serum. The Examiner therefore reasons that one skilled in the art would be motivated to test the inhibitory contributions of serum globulin proteins to identify the factor(s) responsible for growth inhibition. Applicants respectfully disagree.

Applicants note that Furuya et al. was published in 1989 and Hoffman et al. was published as early as 1954 (more recently in 1970). If the identification of IgA and IgM was an obvious undertaking as suggested by the Examiner, Applicants submit that such a discovery would have taken a much shorter period of time. As discussed in Example 17, prior documents have suggested a serum-borne growth inhibiting factor(s) but had yet to identify its existence. More specifically, Soto et al. (*J. Steroid Biochem. Molec. Biol.* Vol. 43, No. 7, pp. 703-712 (1992)) attempted such an undertaking and published their unsuccessful results in 1992. Thus, almost three full years after the Furuya et al. publication, those skilled in the art were unable to purify these serum-borne growth inhibiting factor(s). In fact, Soto et al. presents evidence which would lead one skilled in the art away from IgA and IgM as the growth inhibiting factors. Soto et al. state that “[e]strocolyone-I activity seems to be due to a protein of an apparent native M_w of 70-80 kDa...” See Soto et al. at page 703, Summary, last full sentence. It is well known in the art that IgA (dimer) has a molecular weight of 320kDa and IgM has a molecular weight of 900kDa, which are both well outside the range stated by Soto et al. Moreover, Soto et al. state that “[f]urther purification of estrocolyone-I is being pursued, a step necessary for a mechanistic understanding of its action and that of estrogens on the control of cell proliferation.” See Soto et al. at page 711 last sentence. Thus, Soto et al., which was submitted with the previous Response to Office Action filed August 23, 2010, serves as evidence showing the failure of others in achieving the presently claimed methods.

In view of the above, Applicants respectfully submit that a proper case of obviousness has not been established. Withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing, it is submitted that all rejections have been overcome. Withdrawal of the rejections and allowance of the claims are solicited.

Request for Interview

In the event that the Examiner finds any reason that the application cannot be allowed in its present form, the Applicant wishes to conduct an interview with the Examiner prior to any further action in order to provide an opportunity for coming to agreement upon allowable claims. To arrange the interview, the Examiner is requested to call the undersigned attorney at the telephone number given.

Respectfully submitted,

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By



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